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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/754,125	01/05/01	GELBER	D XMP 2032

HM22/0605

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EXAMINER	
OZGA, B	
ART UNIT	PAPER NUMBER
1651	3

DATE MAILED: 06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/754,125	GELBER ET AL.	
	Examiner	Art Unit	
	Brett T Ozga	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) *1-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 USC 121:

I. Claims 1-55, drawn to compositions comprising a pain reliever and anti-inflammatory, classified in class 424, subclass 729.

II. Claims 56-110, drawn to methods for treating an ailment or symptom caused by an immune response, classified in class 424, subclass 729.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are methods for treating an ailment or symptom caused by an immune response in which one uses different pain relievers and anti-inflammatories than the instant application, such as a narcotic.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Terry Kramer on 3/19/01, a provisional election was made with traverse to prosecute the invention of Group II, claims 56-110. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56-110 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain, coughing and minor symptoms of colds, flu and allergies, does not reasonably provide enablement for treating all ailments or symptoms caused by an immune response, such as autoimmune diseases like Multiple Sclerosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The problem is that the specification addresses minor symptoms of immune response while the scope of the claims encompasses not only these minor symptoms but also any major symptoms of various autoimmune disorders and, potentially, any symptom of immune response. For

example, the symptoms exhibited by and treatments for one suffering from colds, flu or allergies are far removed from the symptoms of autoimmune diseases, such as a combination of analgesics and antihistamines for one suffering from colds, flu or allergies versus gamma-globulin infusions as a treatment for peripheral neuropathy. Furthermore, the symptoms and treatments vary widely even between various autoimmune diseases. The differences in the state of the art of the treatment of life-threatening autoimmune diseases are significantly unpredictable such that the showing of record is insufficient to provide enablement to the scope of the claims of record.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 56-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al. (USP #5260066) in view of Rencher (USP #5462749), Wei et al. (Nutr. Res. (N. Y.) (1998), Yamakazi et al. (USP #5531992) and Tencza et al. (US 4507276)

The instant application teaches a method of treating an ailment or symptom caused by an immune response comprising the step of administering to the patient a medicinal composition, said medicinal composition comprising: a pharmaceutical, a

nutraceutical and an acceptable base. Dependent claims further limit the invention by selecting the pharmaceuticals, including pain relieving and anti-inflammatory agents, from acetaminophen and NSAID's, respectively. They also limit by selecting the nutraceutical from a group including garlic as well as a nutraceutical liver protectant, milk thistle. They also further limit by adding an additional pharmaceutical selected from antihistamines including diphenhydramine and decongestants.

Wood et al. teach phenylpropanolamine, pseudoephedrine, ephedrine, phenylephrine, naphazoline, oxymetazoline, tetrahydrozoline, xylometazoline, propylhexedrine and L-desoxyephedrine as decongestants in a method of treating a cough.

Rencher teaches a method of treating a patient suffering from pain resulting from an inflammatory response with acetaminophen or NSAID's. (See col. 3, first full paragraph)

Wei et al. teaches a method of treating a patient suffering from inflammatory disease, which cause pain, with garlic, an antioxidant. (See abstract)

Yamakazi et al. teach a method of treating a patient suffering from pain and inflammatory disease with milk thistle, an immune booster. (See col. 9, fourth paragraph and Tables 3 and 4)

Tencza et al. teach diphenhydramine and zinc in a method of analgesia. (See col. 3, lines 48 and 52)

Examiner takes Official Notice that the applicant's claimed immune boosters, antioxidants, pharmaceuticals and nutraceuticals are well known in the art.

The scope of the instant application's claim is broad enough to encompass treating pain, coughing and minor symptoms of colds, flu and allergies caused by an immune response. Given that the immune response is a product of the affected's own immune system (such as the release of histamines from basophils) and not necessarily inherent in the causative agent, it would have been obvious to use the above methods that treat pain, coughing and minor symptoms of colds, flu and allergies as a method of treating an ailment or symptom caused by an immune response.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

BTO
June 4, 2001

JEAN C. WITZ
PRIMARY EXAMINER